

DEC 5 2005

November 8, 2005

10. 510(k) SUMMARY

10.1 Summary Information

10.1.1 Submitter's Name and Address

Noble Fiber Technology
300 Palm Street
Scranton, PA 18505

Contact Person and telephone number:

William McNally
Telephone: 877-978-2842
Telefax: 877-978-2842

Date Summary was Prepared

November 8, 2005

10.1.2 Name of Device

OTC Name: SILVERSEAL® SILVERAID™ with X-STATIC®
Professional Trade Name: SILVERSEAL® Adhesive Strip with X-Static®
Common Name: Silver-nylon adhesive strip
Classification Name: Wound and burn dressing

10.1.3 Identification of predicate device to which substantial equivalence is being claimed

SILVERSEAL® Adhesive Strip with X-Static® is a flexible, non-adherent, protective dressing consisting of nylon fibers with a metallic silver surface. It is substantially equivalent to SILVERSEAL® Contact Wound Dressing with X-Static® (K033587), Silverlon Adhesive Strips and Wound Contact Dressings (K023612, K981299, K023609), and Curad Silver Bandage (K032463) with respect to function, intended use, and composition.

10.1.4 Device Description

Explanation of how the device functions: SILVERSEAL® Adhesive Strips with X-Static® are designed to intimately contact the wound as a primary dressing and permit the passage of fluids. The silver provides effective protection of the dressing against microbial contamination.

Basic scientific concepts that form the basis for the device:
The nylon fabric permits the passage of oxygen and fluids to and from the wound. The surface of the nylon fibers in SILVERSEAL® Adhesive Strips with X-Static® consists of a thin layer of approximately 22% metallic silver containing approximately 1.5%

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silver oxide that provides effective protection of the dressing against microbial contamination.

Significant physical and performance characteristics of the device such as device design, materials used, and physical properties: SILVERSEAL® Adhesive Strips are made of flexible, sterile, non-adherent fabric consisting of a knitted continuous nylon fiber substrate with 22% metallic silver surface containing approximately 1.5% silver oxide.

10.1.5 Statement of the intended use of the device, including general description of the conditions the device will mitigate and the patient population for which the device is intended

For over-the-counter use, SILVERSEAL® Adhesive Strips are sterile dressings used in first aid to help in minor abrasions, minor cuts, lacerations, scrapes, minor scalds and burns. For the professional wound care market, SILVERSEAL® Adhesive Strips are indicated for local management of partial thickness burns, incisions, skin grafts, donor sites, lacerations, abrasions, and Stage I-IV dermal ulcers (vascular, venous, pressure and diabetic).

10.1.6 Statement of how the technological characteristics of the device compare to those of the predicate device

The technological characteristics of the device, such as flexible primary contact wound dressing, permeability to oxygen and fluids, and protection against microbial contamination of the dressing that are substantially equivalent to the predicate devices cited.

10.2 Assessment of Performance Data

SILVERSEAL® Adhesive Strips with X-Static® were subjected to standard in vivo biocompatibility tests including cytotoxicity, sensitization, and acute intracutaneous reactivity. All tests were performed in accordance with Part-10993 of the International Standard Organization (ISO) Standard (Biological Evaluation of Medical Devices) by North American Science Associates, Inc. (NAMSA). All claims are the result of In Vitro studies and have not been studied in a clinical setting. The studies indicated that SILVERSEAL® Adhesive Strips with X-Static® are safe for their intended use.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 5 2005

Patricia Davidson
Noble Fiber Technologies, Inc.
421 South State Street
Clarks Summit, Pennsylvania 18411

Re: K050726

Trade/Device Name: SILVERSEAL® SILVERAID™, SILVERSEAL® Adhesive Strip
with X-Static®, Silver-nylon adhesive strip, Wound and burn dressing

Regulatory Class: Unclassified

Product Code: FRO

Dated: November 8, 2005

Received: November 9, 2005

Dear Ms. Davidson:

We have reviewed your Section 510(k) premarket notification of intent to market the devices referenced above and have determined the device are substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

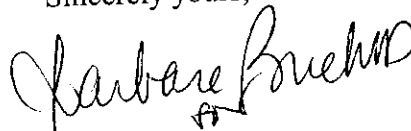
If your devices are classified (see above) into either class II (Special Controls) or class III (PMA), they may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your devices comply with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your devices as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your devices to a legally marketed predicate device results in a classification for your device and thus, permits your devices to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Mark N. Melkerson", with a stylized flourish at the end.

Mark N. Melkerson
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K050726

Device Name:

SILVERSEAL® SILVERAID™
SILVERSEAL® Adhesive Strip with X-Static®
Silver-nylon adhesive strip
Wound and burn dressing

Indications For Use:

For over-the-counter use, SILVERSEAL® Adhesive Strips with X-Static® may be used for:

First aid to help in minor abrasions, minor cuts, lacerations, scrapes, minor scalds and burns.

Under the supervision of a health care professional, SILVERSEAL® Adhesive Strips may be used for the management of:

SILVERSEAL® Adhesive Strips with X-Static® are sterile, non-adherent dressings intended for local management of partial thickness burns, incisions, skin grafts, donor sites, lacerations, abrasions, and Stage I-IV dermal ulcers (vascular, venous, pressure and diabetic).

Prescription Use X
(Part 21 CFR 801 Subpart D)

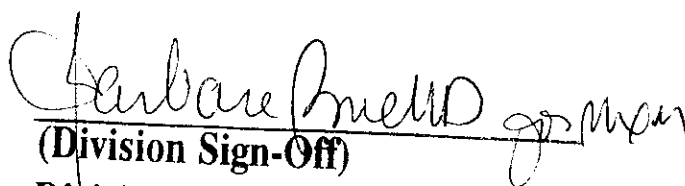
AND/OR

Over-The-Counter Use X
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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(Division Sign-Off)

Division of General, Restorative,
and Neurological Devices

510(k) Number K050726